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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SAUNDERS, DAVID A

ART UNIT PAPER NUMBER

1644

DATE MAILED: 07/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/986,568

Applicant(s)

BACH ET AL.

Examiner

David A. Saunders, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19, 22-24 and 26-33 is/are rejected.
- 7) ☒ Claim(s) 20, 21 and 25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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The response of 3/24/05, filed under 37 CFR 40.50 (b)(1) has been entered.

Claims 19-33 are pending and under examination; the claims are free of new matter.

The 112, first paragraph, written description rejection of record, in the examiner's answer mailed 11/20/03, is not applicable to new claims 19-33.

The 112, first paragraph, enablement rejection and the 103 rejection stated in the examiner's answer have been withdrawn due to the decision of the BPAI mailed 1/26/05.

A rejection under 112, first paragraph is stated infra, based upon the rejection stated by the BPAI under 37 CFR 41.50(b).

Claims 22-23 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The disclosure is non-enabling for the treatment of psoriasis.

Claims 19, 24 and 27-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating diabetes, does not reasonably provide enablement for a method of treating psoriasis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. As stated by the BPAI (decision mailed 1/26/05, in adequate direction has been

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provided for the treatment of autoimmune diseases in general, or any particular autoimmune disease other than diabetes.

Applicant's response of 3/24/05 has presented a declaration filed under 37 CFR 1.132; this declaration was executed by Dr Vaickus to show that treatment of psoriasis was enabled.

The examiner finds the Vaickus declaration inadequate to overcome the enablement issue raised by the BPAI. It is noted that the psoriasis patients were administered a non-mitogenic antibody against CD3, which antibody has been designated as TRX4. The TrX4 antibody was administered at a dose of 1 mg (see paragraph 3, 5, 8 and 9); this dose lies outside the range of 5 to 20 mg taught by applicant (specification page 4 lines 13-20). The clinical trials conducted by Dr. Vaickus thus have not followed the teachings of the instant disclosure.

Additionally the Vaickus declaration is vague about the nature of other medications that the psoriasis patients may have been receiving during the trials conducted with the TRX 4 antibody. Paragraph 4 merely states that "none of the patients had received any systemic agents for psoriasis treatment or any potent immunosuppressive agents..." This statement says nothing as to whether or not any topical agents and/or non-immunosuppressive agents were used during the trials. It is noted that psoriasis is typically treated (see Merck Manual) by the topical application, not the systemic administration, of various agents, including those that are not immunosuppressive. Thus from Vaickeus's vague statement in paragraph 4, there is no indication that treatments with topical agents were halted during the trial. Given the

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absence of such information, one cannot know whether the TRX4 antibody per se was what brought about the decrease in PSAI scores or whether a synergistic effect of the TRX4 antibody and a topical agent was what brought about this decrease. In the latter case, the treatment with the antibody would have been conducted with a combination of the antibody and a secondary agent that was not originally disclosed.

Since the Vaickus declaration has not clearly reported a clinical trial that was conducted according to the teachings of the disclosure, the declaration is not effective in showing the treatment of psoriasis. Also one cannot determine from the declaration whether Dr. Vaickus had ever read the instant disclosure and was familiar with its guidelines.

The prior art of Chatennoud et al (1995), cited in the IDS submitted 3/24/05 has been noted. Like Chatennoud et al (1994), cited in the examiner's answer of 11/12/03, the 1995 reference merely shows treatment of mice. Therefore claims to the treatment of humans are not obvious over this reference.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Saunders whose telephone number is (571) 272-0849. The examiner can normally be reached on Monday to Thursday from 8 AM to 5:30 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Saunders/LR
June 9, 2005

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 1615-1644